

AUG 16 2006

Application No.: 09/623,533

2

Docket No.: 500862001520

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application:

**Claim 1** (previously presented): An anti-viral peptide-albumin conjugate comprising: an anti-viral peptide comprising a maleimide containing group and an amino acid sequence, wherein said sequence is selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541, wherein said sequence exhibits an anti-viral activity against human immunodeficiency virus (HIV) and said peptide is covalently bonded to cysteine 34 of albumin through said maleimide containing group to form said peptide-albumin conjugate wherein the ratio of peptide to albumin in said conjugate is 1:1.

**Claim 2-3** (canceled).

**Claim 4** (previously presented): The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 1.

**Claim 5** (canceled).

**Claim 6** (previously presented): The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541.

**Claims 7-18** (canceled).

**Claim 19** (previously presented): A composition for use in the treatment of acquired immune deficiency syndrome (AIDS) comprising, in a physiologically acceptable medium, an anti-viral peptide-albumin conjugate comprising an anti-viral peptide comprising a maleimide containing group and an amino acid sequence wherein said sequence is selected from the group consisting of

SEQ ID NO: 1 = DP178 = T20 → GAVE THROUGH  
(36 AA) CLINICAL TRIALS /  
ON THE MARKET

PAGE 4/10 \* RCVD AT 8/16/2006 6:00:29 PM [Eastern Daylight Time] \* SVR:USPTO-EFXRF-3/20 \* DNIS:2738300 \* CSID:415 2687522 \* DURATION (mm:ss):03:00

3-5 DP178 ANALOGS (OTHER HIV-1 INHIBITORS)

117-119 DP178 ΔNH<sub>2</sub> PEPTIDES

534-541 DP178 ΔCO<sub>2</sub> + ANALOGS

→ NOT REQUIRED  
AS STATE OF  
CONJUGATION

→ AMINO ACIDS ARE  
MORE STABLE THAN  
THIOESTERS  
→ PROVIDES ANY DATA/ONE  
THAT THIS IS

PARALLEL PEPTIDES  
HAVE ALL BEEN TESTED  
→ IN VITRO FOR HIV  
INHIBITION

PAT  
3116944  
4981979  
6329336  
6887470  
7090851

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SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541, wherein said sequence exhibits an anti-viral activity against human immunodeficiency virus (HIV) and said peptide is covalently bonded to cysteine 34 of albumin through said maleimide containing group to form said anti-viral peptide-albumin conjugate, wherein the ratio of peptide to albumin in said conjugate is 1:1.

**Claim 20** (canceled).

**Claim 21** (previously presented): The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 1.

**Claims 22-30** (canceled).

**Claim 31** (previously presented): The composition of claim 19 wherein said amino acid sequence is selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541.

**Claims 32-35** (canceled).

**Claim 36** (previously presented): A composition comprising the anti-viral peptide-albumin conjugate of claim 1 in a physiologically acceptable medium.

**Claim 37** (canceled).

**Claim 38** (previously presented): The composition of claim 36 wherein said amino acid sequence is SEQ ID NO: 1.

**Claim 39** (previously presented): The composition of claim 36 wherein said amino acid sequence is selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO:

Table 13 shows HPV3 F1 region DP 178 analog amino truncations including SEQ ID NO:447-475.

Table 14 shows HPV3 F1 region DP107 analog carboxy truncations including SEQ ID NO:476-504.

5           Table 15 shows HPV3 F1 region DP107 analog amino truncations including SEQ ID NO:505-533.

Table 16 shows representative anti-RSV peptides of SEQ ID NO:15-30.

Table 17 shows representative anti-HPV3 peptides of SEQ ID NO:33-62.

Table 18 shows representative anti-SIV peptides of SEQ ID NO:64-73.

10           Table 19 shows representative anti-MeV peptides of SEQ ID NO:76-86.

#### **BRIEF DESCRIPTION OF SEQUENCE LISTING**

The invention will be better understood by reference to the Sequence Listing, in which:

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SEQ ID NO:1 shows the peptide sequence of DP178;

SEQ ID NO:2 shows the peptide sequence of DP107;

SEQ ID NO:3-7 show peptide sequences of certain DP178 analogs;

SEQ ID NO:8-9 show peptide sequences of certain DP107 analogs;

a/ 20           SEQ ID NO:10-30 show the peptide sequences of RSV F1 region and F2 region corresponding to DP178 and DP107, and representative anti-RSV peptides;

SEQ ID NO:31-62 show the peptide sequences of HPIV3 F1 region corresponding to DP178 and DP107, and representative anti-HPIV3 peptides;

25           SEQ ID NO:63-73 show peptide sequences of SIV corresponding to DP178 and representative anti-SIV peptides;

SEQ ID NO:74-86 show peptide sequences of MeV corresponding to DP178 and representative anti-MeV peptides;

SEQ ID NO:87-116 show peptide sequences of DP178 carboxy truncations;

30           SEQ ID NO:117-146 show peptide sequences of DP178 amino truncations;

SEQ ID NO:147-178 show peptide sequences of DP107 carboxy truncations;

SEQ ID NO:179-210 show peptide sequences of DP107 amino truncations;

5 SEQ ID NO:211-240 show peptide sequences of HIV-2<sub>NIH2</sub> DP178 analog carboxy truncations;

SEQ ID NO:241-270 show peptide sequences of HIV-2<sub>NIH2</sub> DP178 analog amino truncations;

10 SEQ ID NO:271-312 show peptide sequences of RSV F2 region DP107 analog carboxy truncations;

SEQ ID NO:313-353 show peptide sequences of RSV F2 region DP107 analog amino truncations;

SEQ ID NO:354-385 show peptide sequences of RSV F1 region DP178 analog carboxy truncations;

15 a/ SEQ ID NO:386-416 show peptide sequences of RSV F1 region DP178 analog amino truncations;

SEQ ID NO:417-446 show peptide sequences of HPV3 F1 region DP 178 analog carboxy truncations;

20 SEQ ID NO:447-475 show peptide sequences of HPV3 F1 region DP 178 analog amino truncations;

SEQ ID NO:476-504 show peptide sequences of HPV3 F1 region DP107 analog carboxy truncations;

SEQ ID NO:505-533 show peptide sequences of HPV3 F1 region DP107 analog amino truncations;

25 SEQ ID NO:534-541 show peptide sequences of DP178 with deletion and insertion of an amino acid; and

SEQ ID NO:542-545 show peptide sequences of DP107 with deletion and insertion of an amino acid.

HPIV -- HPIV-1, HPIV-2, HPIV-3 and HPIV-4. HPIV-1 is the leading cause of croup in children, and both HPIV-1 and HPIV-2 cause upper and lower respiratory tract illnesses. HPIV-3 is more often associated with bronchiolitis and pneumonia.

Anti-HPV peptides are peptides that exhibit anti-viral activity against HPV, including inhibiting infection by free HPV virus and syncytia formation between infected and uninfected cells.

**MeV and anti-Mev peptides:** Measles virus (VM or MeV) is an enveloped negative, single-stranded RNA virus belonging to the *Paramyxoviridae* family of viruses. Like RSV and HPV, MeV causes respiratory disease, and also produces an immuno-suppression responsible for additional, opportunistic infections. In some cases, MeV can establish infection of the brain leading to severe neurological complications. Anti-MeV peptides are peptides that exhibit anti-viral activity against MeV, including inhibiting infection by free MeV virus and syncytia formation between infected and uninfected cells.

**DP-178 and DP178 analogs:** Unless otherwise indicated explicitly or by context, DP-178 means the 36 amino acid DP-178 peptide corresponding to amino acid residues 638-673 of the gp41 glycoprotein of HIV-1 isolate LAI (HIV<sub>LAI</sub>) and having the sequence:

YTSLIHSLIEESQNQQEKNEQELLELDKWASLWNWF (SEQ ID NO:1)

as well as truncations, deletions and/or insertions thereof. Truncations of the DP178 peptide may comprise peptides of between 3-36 amino acids. Deletions consist of the removal of one or more amino acid residues from the DP178 peptide, and may involve the removal of a single contiguous portion of the peptide sequence or multiple portions. Insertions may comprise single amino acid residues or stretches of residues and may be made at the carboxy or amino terminal end of the DP178 peptide or at a position internal to the peptide.

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AMENDMENTS TO THE CLAIMS 1, 4, 6, 19, 21, 31, 36,  
38, 39, 59-88

This listing of claims replaces all prior versions and listings of claims in the application:

5464933  
6020459?  
6133418  
6258782  
W094/28720  
✓ Claim 1 (previously presented): An anti-viral peptide-albumin conjugate comprising: an anti-viral peptide comprising a maleimide containing group and an amino acid sequence, wherein said sequence is selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541, wherein said sequence exhibits an anti-viral activity against human immunodeficiency virus (HIV) and said peptide is covalently bonded to cysteine 34 of albumin through said maleimide containing group to form said peptide-albumin conjugate wherein the ratio of peptide to albumin in said conjugate is 1:1.

Claim 2-3 (canceled).

SEQ 118:

4,536,391  
5,242,680

Claim 4 (previously presented): The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 1.

Claim 5 (canceled).

MALEIMIDE? CONJUGATE?  
PEPTIDE? ALBUMIN?

Claim 6 (previously presented): The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541.

1 - F2113A 117 - 638<sup>782</sup> 535 - 15<sup>782</sup> 539  
3 - 135<sup>782</sup> 118 - 800<sup>782</sup> 536 - 15<sup>782</sup> 540 - 15<sup>782</sup>  
4 - 1515<sup>782</sup> 119 - 62<sup>782</sup> 537 - 642<sup>782</sup> 541 - 15<sup>782</sup>  
5 - 51933 534 - 15<sup>782</sup> 538 - 15<sup>782</sup>

Claims 7-18 (canceled).

Claim 19 (previously presented): A composition for use in the treatment of acquired immune deficiency syndrome (AIDS) comprising, in a physiologically acceptable medium, an anti-viral peptide-albumin conjugate comprising an anti-viral peptide comprising a maleimide containing group and an amino acid sequence wherein said sequence is selected from the group consisting of

SEQ 118: 74 '933; 234 '459

SEQ 4:

1, 3, 4, 5, 117, 118, 119 → '933

534 - 541 →

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SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541, wherein said sequence exhibits an anti-viral activity against human immunodeficiency virus (HIV) and said peptide is covalently bonded to cysteine 34 of albumin through said maleimide containing group to form said anti-viral peptide-albumin conjugate, wherein the ratio of peptide to albumin in said conjugate is 1:1.

Claim 20 (canceled).

Claim 21 (previously presented): The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 1.

Claims 22-30 (canceled).

Claim 31 (previously presented): The composition of claim 19 wherein said amino acid sequence is selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO: 536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541.

Claims 32-35 (canceled).

Claim 36 (previously presented): A composition comprising the anti-viral peptide-albumin conjugate of claim 1 in a physiologically acceptable medium.

Claim 37 (canceled).

Claim 38 (previously presented): The composition of claim 36 wherein said amino acid sequence is SEQ ID NO: 1.

Claim 39 (previously presented): The composition of claim 36 wherein said amino acid sequence is selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 117, SEQ ID NO: 118, SEQ ID NO: 119, SEQ ID NO: 534, SEQ ID NO: 535, SEQ ID NO:

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536, SEQ ID NO: 537, SEQ ID NO: 538, SEQ ID NO: 539, SEQ ID NO: 540, and SEQ ID NO: 541.

**Claims 40-58 (canceled).**

**Claim 59 (currently amended):** The anti-viral peptide-albumin conjugate of claim 1 wherein said albumin is in-blood serum albumin.

**Claim 60 (currently amended):** The anti-viral peptide-albumin conjugate of claim 59 wherein said blood is in a albumin is human serum albumin.

**Claim 61 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 3.

**Claim 62 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 4.

**Claim 63 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 5.

**Claim 64 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 117.

**Claim 65 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 118.

**Claim 66 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 119.

**Claim 67 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 534.

**Claim 68 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 535.



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**Claim 69 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 536.

**Claim 70 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 537.

**Claim 71 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 538.

**Claim 72 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 539.

**Claim 73 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 540.

**Claim 74 (previously presented):** The anti-viral peptide-albumin conjugate of claim 1 wherein said amino acid sequence is SEQ ID NO: 541.

**Claim 75 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 3.

**Claim 76 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 4.

**Claim 77 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 5.

**Claim 78 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 117.

**Claim 79 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 118.

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**Claim 80 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 119.

**Claim 81 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 534.

**Claim 82 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 535.

**Claim 83 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 536.

**Claim 84 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 537.

**Claim 85 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 538.

**Claim 86 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 539.

**Claim 87 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 540.

**Claim 88 (previously presented):** The composition of claim 19 wherein said amino acid sequence is SEQ ID NO: 541.

native sequences are found, or may exhibit an ability to modulate intracellular processes involving coiled-coil peptide structures.

**A. DP178 analogs**

5 DP178 analogs are peptides whose amino acid sequences are comprised of the amino acid sequences of peptide regions of, for example, other (i.e., other than HIV-1) viruses that correspond to the gp41 peptide region from which DP178 was derived. Such viruses may include, but are not limited to, other HIV-1 isolates and HIV-2 isolates.

10

DP178 analogs derived from the corresponding gp41 peptide region of other (i.e., non HIV-1LAI) HIV-1 isolates may include, for example, peptide sequences as shown below.

15 NH<sub>2</sub>-YTNTIYTLLEESQNQQEKNEQELLELDKWASLWNWF-COOH (SEQ ID NO:3)

NH<sub>2</sub>-YTGIIYNLLEESQNQQEKNEQELLELDKWANLWNWF-COOH (SEQ ID NO:4)

20 NH<sub>2</sub>-YTSLIYSLLEKSQIQQEKNEQELLELDKWASLWNWF-COOH (SEQ ID NO:5)

The peptides of SEQ ID NO:3, SEQ ID NO:4 and SEQ ID NO:5 are derived from HIV-1<sub>SF2</sub>, HIV-1<sub>RF</sub>, and HIV-1<sub>MN</sub>, respectively. Other DP178 analogs include those derived from HIV-2, including the peptides of SEQ ID NO:6 and  
25 SEQ ID NO:7, which are derived from HIV-2<sub>ROD</sub> and HIV-2<sub>NH2</sub>, respectively. Still other useful analogs include the peptides of SEQ ID NO:8 and SEQ ID NO:9, which have been demonstrated to exhibit anti-viral activity.

30 In the present invention, it is preferred that the DP178 analogs represent peptides whose amino acid sequences correspond to the DP178 region of the gp41

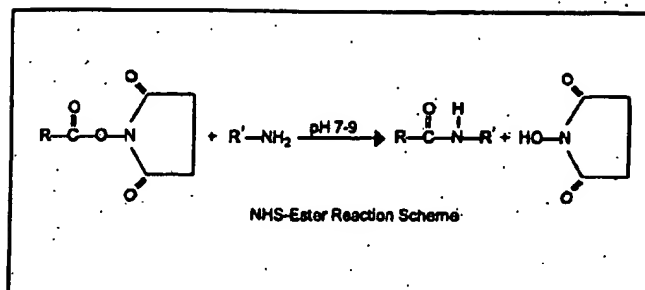
005060.22522960

	EESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:125
	IEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:124
	LEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:123
	SLIEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:122
5	HSLIEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:121
	IHSLIEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:120
	LIHSLIEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:119
	SLIHSLIEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:118
	TSLIHSLIEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:117
10	YTSLIHSLIEESQNQQEKNEQEELLELDKWASLWNWF	SEQ ID NO:1

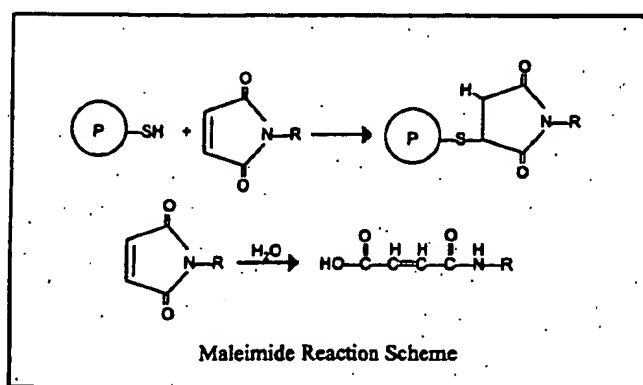
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The one letter amino acid code of Table 1 is used.

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In the preferred embodiments of this invention, the functional group on this protein will be a thiol group and the chemically reactive group will be a maleimido-containing group such as MPA or GMBA (gamma-maleimide-butyralamide). The maleimido group is most selective for sulfhydryl groups on peptides when the pH of the reaction mixture is kept between 6.5 and 7.4. At pH 7.0, the rate of reaction of maleimido groups with sulfhydryls is 1000-fold faster than with amines. A stable thioether linkage between the maleimido group and the sulfhydryl is formed which cannot be cleaved under physiological conditions, as demonstrated in the following schematic.



#### A. Specific Labeling.

Preferably, the modified peptides of this invention are designed to specifically react with thiol groups on mobile blood proteins. Such reaction is preferably established by covalent bonding of the peptide modified with a

005060-EESE22960

DP-178 C

Fmoc-Rink Amide MBHA Resin

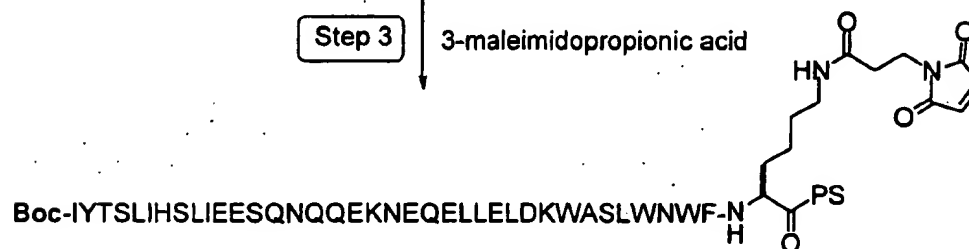
Step 1 ↓ SPPS

Boc-YTSLIHSLIEESQNQQEKNEQELLELDKWASLWNWF-Lys(Aloc)-PS

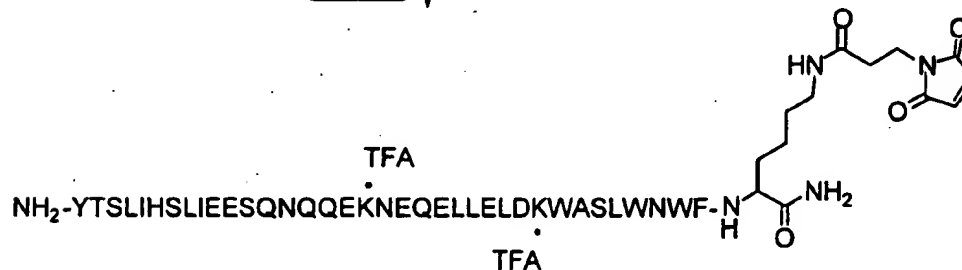
Step 2 ↓ Pd(PPh<sub>3</sub>)<sub>4</sub>/NMM/HOAc/CHCl<sub>3</sub>

Boc-YTSLIHSLIEESQNQQEKNEQELLELDKWASLWNWF-Lys-PS

Step 3 ↓ 3-maleimidopropionic acid



Step 4 ↓ 85% TFA/5% TIS/5% thioanisole/5% phenol



Example 2

5 Preparation of a Modified DP107--Synthesis of  
NNLLRAIEAQHLLQLTVWQIKQLQARILAVERYLKDQK(MPA)NH<sub>2</sub>

In this example, DP107 (SEQ ID NO:2) is synthesized and modified to